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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,900	08/27/1999	ALVARO J. LAGUNA	MP/147	8440

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EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EE

Office Action Summary

Application No.

09/384,900

Applicant(s)

LAGUNA ET AL.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Product by Process Claims

Claims 28, 29, 36, and 37 are product by process claims and although the claims are definite according to 35 USC 112 2nd paragraph, no patentable weight is given to the process by which the device was made. See below for further discussion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24-26, 29, 32, 37, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Glickman (US 5,919,163).

Art Unit: 3763

Glickman teaches all the claimed subject matter including a piece of tubing made out of elastomeric material (col. 16, lines 43-52), which is positioned on a catheter shaft to form a balloon which is slidable along the shaft while maintaining a "fluid tight seal" (claim 8). The fact that the ends of the balloon remain tight against the catheter shaft but are movable along it, indicates that they are non-distensible as compared to the rest of the balloon, and that the balloon is a separate piece of equipment that maintains those properties of distensibility even when not mounted on a catheter. Glickman also teaches attachment of the balloon to the catheter with adhesive (col. 16, lines 46-48).

Instant claims 29 and 37 are product by process claims and thus the process (thermally treating) is not given patentable weight. With regard to claims 32 and 40, Glickman meets the limitations of these claims since it teaches a balloon with non-distensible ends, attached to a non-distensible catheter via adhesive (col. 16, lines 46-48; element 108 on slidable balloon 110 can be adhesively attached to catheter shaft).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 34, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman (US 5,919,163) in view of Campbell et al (US 5,868,704).

Art Unit: 3763

Glickman teaches all the claimed subject matter except for the sleeve being made out of a fluoropolymer. Campbell teaches a balloon made out of polytetrafluoroethylene (claims). Fluoropolymers such as polytetrafluoroethylene (PTFE) are well-known to be used to make catheters, as illustrated by Campbell. It would have been obvious to use PTFE to make the sleeve of Glickman, since it would perform equally as well as the disclosed material. Also note that both Glickman and Campbell teach that a possible alternative material that can be used to form the balloon is polyurethane (Glickman, col. 16, line 46; Campbell, col 3, line 26). Again, materials such as PTFE, polyurethanes, and polyethylenes are extremely common in the art of catheters/balloons.

Claims 28, 30, 31, 36, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman (US 5,919,163) in view of Crocker et al (US 5,843,116).

Glickman teaches all the claimed subject matter except for the sleeve being coated on the ends or having a collar on the end to render the end non-distensible. Crocker teaches a balloon sleeve with a collar (40/44) to limit expansion. Crocker also teaches that alternative means can be used to limit expansion, such as coatings (col. 5, line 55-58). Since Glickman makes no mention of *how* his balloon ends are made to be non-distensible, it would have been obvious to one of ordinary skill in the art to use collars or coatings in the manner set forth by Glickman to render the balloon ends of Glickman non-distensible as these are equivalent for their use as such and the device would work equally well with any of these structural designs. To further support this

Art Unit: 3763

point, Applicant discloses that any of these expansion-limiting elements can be used to form the instant invention. Applicant's claims and specification basically set forth all the different ways that one could reasonably render the ends of a distensible tubular structure to be non-distensible.

Claims 27 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glickman and Crocker as applied to claims 24 and 25 above, and further in view of Ravenscroft et al (US 5,766,201).

Glickman as modified by Crocker teaches all the claimed subject matter except for tape wrapping the ends of the tubing to render it non-distensible. Ravenscroft teaches tightly wound tape wrapping at the ends of the balloon to render it of a different distensibility than the rest of the balloon (see fig. 1 and col. 1 line 67 – col. 2, line 5). Due to the interchangeability discussed supra and the lack of a teaching in Glickman of how he makes the ends of his balloons non-distensible, one of ordinary skill in the art would have found it obvious to use the tape wrapping of Ravenscroft to render the ends of the Glickman balloon non-distensible.

Response to Arguments

With regard to the rejection issued in the previous office action relying solely on Ravenscroft, the examiner inadvertently left that rejection in from a draft action, and had accordingly removed it from the current office action. All pending claims were and still are addressed by other rejections rendered in the previous office action.

Art Unit: 3763

Applicant argued that Glickman requires the stops within the balloon to prevent the balloon from being slid off the catheter (or being slid onto the catheter prior to rendering the ends non-distensible). However, figure 8 (not 8A or 8B) shows a slidable balloon without the stops. The stops are an *optional* feature.

With regard to the product by process claims, applicant argues that claims 28 and 36 intend to claim a catheter with a coating. If this is the case, then the claims should read "one end has a coating," instead of "one end is coated to..." With regard to claims 29 and 37, thermal treatment is purely a process limitation and carries no patentable weight in an apparatus claim, no matter how it is drafted

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3763

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 306-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt

May 15, 2003



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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